K080906

510(K) SUMMARY

OCT 17 2008

Submitter: CDB Corporation
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Date Prepared: January 22, 2008

Name of device: The CDB Clip – Orthodontic Bracket Accessory

Classification Name Bracket, Ceramic, Orthodontic

Device Classification
Regulatory Class II
Product Code: NJM
Classification Panel: Dental
Regulation Number: 21 CFR 872.5470

Predicate Device(s)

510(k) Number	Device	Manufacturer
K042905	NEO-CLIP ORTHODONTIC BRACKET ACCESSORY	Dentsply International

Device Description The CDB Clip is a passive ligation clip which functions to retain the orthodontic archwire in the slot of an orthodontic bracket. It is made of Celcon MT 24U01 Acetal (POM) with no fillers.

Indications
The CDB Clip, commonly known as an orthodontic ligation clip, is an orthodontic bracket accessory. It attaches to the orthodontic bracket to hold the archwire firmly in the slot. Together they facilitate the orthodontic movement of teeth.

Technological Characteristics The function and performance of the CDB Clip is identical to the predicate device listed above. There is no difference in the fundamental technology. The CDB Clip is made of the same material as the predicate device currently on the market and has the same overall intended use.

Conclusion

By definition, a device is substantially equivalent when the device has the same intended use and the same technological characteristics as the predicate device.

There are no major differences between the CDB Clip and the predicate device cited, therefore, the CDB Clip does not raise any questions regarding the safety and effectiveness.

The CDB Clip, as designed, is as safe and effective as the predicate device and the device is determined to be substantially equivalent to the referenced predicate device currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2008

Mr. Jens Rumsfeld
Managing Director
CDB Corporation
9201 Industrial Boulevard
Leland, North Carolina 28451

Re: K080906
Trade/Device Name: CDB Clip
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NJM
Dated: September 12, 2008
Received: September 16, 2008

Dear Mr. Rumsfeld:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K080906

Indications for Use

510(k) Number (if known): K080906

Device Name: CDB Clip

Indications For Use:

The CDB Clip, commonly known as an orthodontic ligating clip, is an orthodontic bracket accessory. It attaches to the orthodontic bracket to hold the archwire firmly in the slot. Together they facilitate the orthodontic movement of teeth.

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080906

Prescription Use X_____ _ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (OD E)